NMT Medical, Inc.

RNF Design Review II Minutes

Meeting Date:

Friday, April 14, 2000

Meeting Time:

1:30 p.m.

Participants:

Thomas Kinst (TFK), Rob Carr (RMC), Tim Connor (TJC), Alex

Chaharom (EAC), Dennis Goodine (DMG), Michael Goodine (MPG),

Michael Schwartz (MMS)

Purpose:

Complete Design Review II.

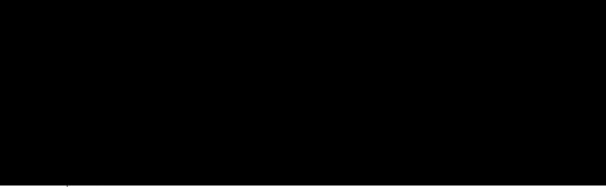
Notes written by Thom Kinst

Introductory Remarks

TFK opened the meeting with introductory remarks including the purpose of the meeting, what the intended outcome will be, and how this Design Review fits into the Design Control SOP (SOP-RD-006).

Review of Design History File

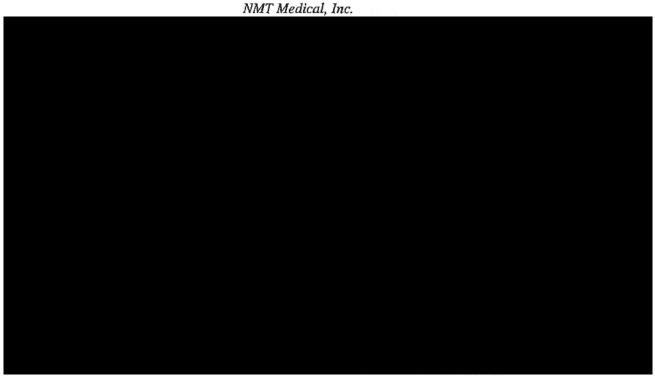
TFK presented a binder (RD-BND-062) that contains the summary of Phase II activities and the locations of where those activities are documented.



Review of Summary of Design Verification Studies

Review		
Action Items		N

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Review of Biocompatibility Studies

Review

The biocompatibility studies performed on the Recovery Filter and Recovery Cone systems were summarized presented. The biocompatibility data for the Simon Nitinol Filter implant was used to support biocompatibility of the Recovery Filter implant due to equivalent materials and manufacturing processes. The biocompatibility data for the SNF/SL introducer sheath was used to support biocompatibility of the Recovery Filter introducer sheath because the same materials and procedures were used, only the location of the proximal band was different. The biocompatibility test results for the Recovery Cone, Recovery Filter pusherwire, and Recovery Cone introducer sheath with PtIr bands were presented.

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Review of Design and Process FMEA's

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Action Items		
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Review of the Design Output	Document
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Review		1	
Action Items			
Review of the Product	Performance Specifi	cations	
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Review			
Review of the Product Review Action Items			
Review			
Review			
Review			

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ACTION ITEMS: Design Review II 14 April 2000

